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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 08/928,074 | 09/11/1997 | FREDERICK FISH | 07256-024001 | 9183 |

20985 7590 07/21/2003

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| EXAMINER | |
|---|---|
| HAYES, ROBERT CLINTON | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 07/21/2003

JG

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 08/928,074 | Applicant(s) O'Brien |
|---|---|---|
| | Examiner Robert C. Hayes, Ph.D. | Art Unit 1647 |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *May 9, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *3-8* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *3-8* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed 5/09/03 has been entered. It is suggested that claim 3 be amended to delete the redundant claim language "having from 14 to 50 amino acids", which only confuses that being claimed.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 3-8 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5 & 6-9 of U.S. Patent No. 5,696,080, for the reasons made of record in Paper No.14 (mailed 7/18/00).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the prosaposin fragment of amino acids 8-29 of SEQ ID NO:3 of '080 is identical to SEQ ID NO:1 of the instant application, and in which SEQ ID NO:2 is an "active neurotrophic fragment located within" this sequence (i.e., as it relates to claim 3 of the instant invention and claim 1 of '080), and wherein pharmaceutical compositions are "compositions" by definition, as claimed in '080 (i.e., as it especially relates to claims 5-8 of the instant application versus claims 3, 5, 4 & 8 of '080); thereby, meeting all structural limitations recited in the instant claims, and for the reasons made of record in Paper No.14.

4. Claims 4-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application exists for the recitations of "treating neuropathic pain" or "in an effective amount that is greater than 20 *u*g/kg and less than 100 *u*g/kg of body weight" in base claim 4. In contrast to Applicant's assertions on page 4 of Paper No:16 (amdt D), no such basis exists on page 42, line 28 of the specification, because "diabetic neuropathy" is not equivalent to "neuropathic pain", and because an "optimal dose of [the] prosaptide" [of SEQ ID NO:2] is not equivalent in scope to the different molecular weight polypeptide of SEQ ID NO:1, and because a dose in a "method" that is administered to different animals/patients is not equivalent to a dosage in a pharmaceutical "product" composition.

5. Claims 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "in an effective amount that is greater than 20 *u*g/kg and less than 100 *u*g/kg of body weight" in base claim 4 is ambiguous because different animals/patients are of

different weights, which reasonably cannot be determined before-the-fact for this product claim; especially as it relates to what then constitutes an "unit dosage form" in claim 8.

6. Claims 3-8 stand rejected under 35 U.S.C. 102(e) as being anticipated by O'Brien et al. (US Patent 5,696,080), for the reasons made of record in Paper No.14.

In summary, O'Brien et al. teach saposin C-derived fragments that consist of SEQ ID NO:1 and 2, as well as pharmaceutical compositions of these peptides in "pharmaceutically acceptable carriers (i.e., as it relates to claim 4), in "liposomal form (i.e., as it relates to claim 6), in "lyophilized form (i.e., as it relates to claim 7), in "unit dosage form (i.e., as it relates to claim 8), and using "controlled release materials" (i.e., as it relates to claim 5). It is noted that the intended use recited in claim 4 carries no patentable weight.

7. Claims 3-8 stand rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter, for the reasons made of record in Paper No.14. Again, these claims were disclosed in U.S. Patent No. 5,696,080 to be invented by both O'Brien and Kishimoto, versus O'Brien alone; thereby, still placing the issue of inventorship in question, which needs to be resolved.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCH

Robert C. Hayes, Ph.D.
July 17, 2003

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER